REMARKS

In the Office Action of July 1, 2003, Claims 1 - 30 were rejected. No claim was allowed. In response, Claims 1 - 5, 7 - 9, 11 - 13, 15 - 17, 19 - 23, 25 - 27, 29 and 30 are amended and new Claims 31 - 60 are added to the application. Reexamination and reconsideration are respectfully requested in view of the foregoing amendments and the following remarks.

Rejection of Claims 1 - 30 under 35 U.S.C. §112, first paragraph

Claims 1 - 30 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that is not enabled by the specification. The Examiner alleged that the specification does not show how the applicants determine the presence or absence of an amide bond in the product. In response, the limitation "wherein an new amide bond is not formed by the reaction" is deleted from the claims, thereby obviating the need to show how the presence or absence of an amide bond is determined. Accordingly, it is respectfully submitted that this rejection under 35 U.S.C. §112, first paragraph, is thereby overcome.

Rejection of Claims 1 - 30 under 35 U.S.C. §112, first paragraph

Claims 1 - 30 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that is not enabled by the specification. The Examiner alleged that the specification, while being enabling for peptides, proteins, enzymes and amino acid derivatives, does not provide enablement for all compounds having free amino groups and for all sugars having reducing power. In response, the claims are amended so that the compound having the free amino group is defined

according to what the Examiner has acknowledged is enabled by the specification, specifically, doxorubicin, peptides, proteins, and enzymes, and dopamine. The sugar having reducing power is defined according to the sugars named in the specification on page 5, lines 10 - 30.

Accordingly, it is respectfully submitted that the rejection of Claims 1 - 30 under 35 U.S.C. §112, first paragraph, is thereby overcome.

Rejection of Claims 1 - 30 under 35 U.S.C. §112, second paragraph

Claims 2 and 5 - 30 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Regarding Claim 1, the Examiner alleges that the claim is confusing. In response, the claim is rewritten for greater clarity by, for example, labeling the compounds of the claims by the designations (I), (II) and (III), making it easier to follow which compound is reacting or released from which.

Regarding Claims 1, 5, 9, 13, 17, 23 and 27, the Examiner alleges that the phrase "which can be obtained" is indefinite because it is unclear how the disclosed compound sill be prepared by reacting a compound having free amino group with a sugar having the reducing power. This rejection is traversed. So long as two components, namely, "a compound (II) having a free amino group being selected from the group consisting of doxorubicin, peptides, proteins, enzymes and dopamine" and "a sugar (III) having the reducing power" are reacted to prepare the present phamaceutical preparation, any step for preparing the claimed pharmaceutical preparation maybe applied. Therefore, it is not necessary to delineate every step for preparing the claimed pharmaceutical preparation.

Regarding Claims 1 - 2, 5, 7, 13 and 21, the Examiner alleges that the term "derivatives" is indefinite. In response, this term is deleted from the claims.

Regarding Claim 1, the Examiner alleges that the term "capable" is indefinite. In response, this term is deleted from the claims.

Regarding Claims 5, 9, 13, 17 and 23, the Examiner alleges that the term "modified with or included in" renders the claims indefinite. In response, Claims 5, 9, 13, 17 and 23 are amended to make it clear that four embodiments are included in the preparation according to Claims 5, 9, 13, 17 and 23, respectively.

For example, the following four embodiments ((1) to (4)) are included in the preparation of Claim 5;

(1) at least one of a compound having a free amino group (which is selected from the group consisting of doxorubicin, peptides, proteins, enzymes and dopamine) and a reducing sugar, is modified with a pharmaceutical carrier;

(2) at least one of a compound having a free amino group (which is selected from the group consisting of doxorubicin, peptides, proteins, enzymes and dopamine) and a reducing sugar, is encapsulated in a pharmaceutical carrier

(3) a compound which can be obtained by reacting a compound having a free amino group (which is selected from the group consisting of doxorubicin, peptides, proteins, enzymes and dopamine) with a reducing sugar, is modified with pharmaceutical carrier;

(4) a compound which can be obtained by reacting a compound having a free amino group (which is selected from the group consisting of doxorubicin, peptides, proteins, enzymes and dopamine) with a reducing sugar, is encapsulated in a pharmaceutical carrier.

Regarding Claims 7 - 8, 11 - 12, 15 - 16, 19 - 20, 25 - 26 and 29 - 30, the Examiner alleges that the term "included" renders the claims indefinite. In response, the term "included" is replaced with the term "encapsulated" in claims 7, 8, 11, 12, 15, 16, 19, 20, 25, 26, 29 and 30.

Accordingly, it is respectfully submitted that all of the rejections under 35 U.S.C. §112, second paragraph, are thereby overcome.

Rejection of Claim 1 under 35 U.S.C. §102(b) over Sessler

Claim 1 - 4 was rejected under 35 U.S.C. §102(b) as anticipated by Sessler (U.S. Patent No. 5,580,543). The Examiner alleged that Sessler teaches a pharmaceutical compound comprised of a peptide and a saccharide wherein the peptide is a hormone or enkephalin and the saccharide is D-glucose, D-mannose or D-galactose and that the composition is formed without any amide bonds.

This rejection is respectfully traversed. Although Sessler teaches that texaphyrin having substituents which may be saccharide is coupled to site-directing molecules to form conjugates, and the site-directing molecules (for example, oligodeoxyribonucleotides, peptides having affinity for a biological receptor and the like) are exemplified in the description (Column 6, lines 19-21 and lines 30-38), it is not disclosed in Sessler that a saccharide (not including a texaphyrin moiety) binds to the site directing molecules (corresponding to "a compound (II) having a free amino group" in the present invention).

On the other hand, the claimed preparation of the present invention comprises a compound which can be obtained by reacting a compound (II) having a free amino group selected from the group consisting of doxorubicin, peptides,

proteins, enzymes and dopamine with a sugar (III) having the reducing power selected from the group A. The sugars selected from the group A do not have a texaphyrin moiety in their structure.

Accordingly, it is respectfully submitted that Claim 1 is not anticipated by Sessler.

Rejection of Claim 1 - 30 under 35 U.S.C. §103(a) over Sessler in view of Katsukiyo and Masashi

Claims 1 - 30 were rejected under 35 U.S.C. §103(a) over Sessler in view of Katsukiyo (JP 7-061999) and Masashi (JP 9-263579). The Examiner applies Sessler as discussed above. The Examiner acknowledges that Sessler does not disclose insulin to be the peptide with free amino group and does not disclose a pharmaceutical carrier. The Examiner alleges that Katsukiyo teaches a sugar-modified protein obtain when lactose-lactone is reacted with a protein and describes using insulin as the protein and that the reference inherently teaches that a free protein can be quickly separated through changes in pH. The Examiner alleges that Masashi et al teach medicines made from the enclosing of a drug made from protein inserted into a micro-globule, ribosome, emulsion or other carrier. The Examiner takes the position that it would have been obvious to modify the composition and method of Sessler according to the teachings of Katsukiyo and Masashi because both Sessler and Katsukiyo teach modifying a compound having a free amino group with a reducing sugar wherein upon changes in the pH conditions, the compound with the free amino group is released and because Masahi teaches making a drug by inserting a protein into a microglobule, ribosome, emulsion or other carrier.

This rejection is traversed. As discussed above, Sessler does not disclose nor suggest that a sugar (III) having the reducing power selected from the group A (corresponding to a saccharide in Sessler) binds to the compound (II) having a free amino group selected from the group consisting of doxorubicin, peptides, proteins, enzymes and dopamine.

Although Katsukiyo discloses a sugar-modified protein wherein lactose-lactone is reacted with a protein (a protein is one embodiment of a compound (II) having a free amino group), and Masashi discloses a pharmaceutical preparation made from enclosing a drug made from protein inserted into a liposome etc, the above two references do not disclose nor suggest a combination of a compound (II) having a free amino group and a sugar (III) having the reducing power.

On the other hand, by using a compound prepared by reacting a compound (TI) having a free amino group and a sugar (III) having the reducing power according to the present invention, a pharmaceutical preparation having the unique characteristics to release the compound (II) having a free amino group in response to changes to pH is obtained.

Accordingly, it is respectfully submitted that Claims 1 - 30 would not have been obvious over Sessler, Katsukito and Masashi, alone or in combination.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 1 - 60 are in condition for allowance. Favorable reconsideration is respectfully requested.

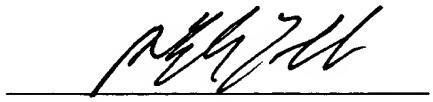
Should the Examiner believe that anything further is necessary to place this

application in condition for allowance, the Examiner is requested to contact applicants' undersigned attorney at the telephone number listed below.

Kindly charge any additional fees due, or credit overpayment of fees, to Deposit Account No. 01-2135 (506.40278X00).

Respectfully submitted,
ANTONELLI, TERRY, STOUT & KRAUS

RTW/RTW
(703)312-6600



Ralph T. Webb
Reg. No. 33,047